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EXAMINER

MORAN, MARJORIE A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/026,110

Applicant(s)

CHENG, JILL

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 13-22, 28-37 and 43-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 13-22, 28-37 and 43-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

5-8-05

Cancellation of claims 8-12, 23-27 and 38-42 in the amendment filed 5/17/05 is acknowledged. An action on the merits of elected claims 1-7, 13-22, 28-37, and 43-45, as they read on the elected species, follows.

Information Disclosure Statement

It is again noted that one or more references have been incorporated into the specification by reference, but have not been supplied to the PTO nor included in a properly filed IDS. Applicant is reminded that a listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. No IDS has been filed as of the date of this Office Action.

Drawings

New Figures 4 and 5 were received on 5/17/05. These drawings are acceptable to the examiner.

Specification

The objections to the abstract and disclosure are hereby withdrawn in view of the new abstract and amendments to the specification filed 5/17/05.

Claim Objections

The claim objections are hereby withdrawn in view of the amendments filed 5/17/05.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7 and 13-15 are again rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Applicant's arguments filed 5/17/05 have been fully considered but they are not persuasive. In response to the argument that lack of a physical result "should not matter" and that a computer-implemented method may be statutory, it is noted that the previous office action stated that .

"In the absence of a physical method step or actual transformation of data, a computer-implemented method MAY be statutory where the claimed method recites a concrete, tangible, and useful result. See MPEP 2106.IV.B.1 and B.2." Thus, the examiner and applicant appear to be in agreement that as the instant claims do not recite a physical step, they must recite a "useful, concrete and tangible result" as set forth in the State Street Bank decision cited on page 17 of the response.

However, as set forth in the previous office action, the instant claims do not actually recite ANY result. The claimed steps are directed to obtaining, selecting, and

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analyzing data, but do not recite any actual output or product from the analysis such that one skilled in the art would know what the result of the analysis is. In response to the argument that "gene cluster analysis" does "provide results of data manipulation", it is admitted that a method of analyzing genes and/or gene clusters MAY provide a concrete, tangible, and useful result. Again, it is noted that no actual result is recited in the instant claims. As no result is recited, the claims do not comply with the requirement for a "concrete, tangible and useful result", therefore the examiner maintains that the claims do not recite statutory subject matter.

Claims 1-7, 13-22, 28-37 and 43-45 are again rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an asserted utility or a well established utility.

Applicant's arguments filed 5/17/05 have been fully considered but they are not persuasive.

The instant specification does not disclose any utility for merely analyzing gene expression data. In response to the argument that a well-established utility is supported by the prior art; i.e. a use to perform research to analyze massive amount of data from experiments for study of diseases, it is acknowledged that analysis of molecular biology data for purposes of identifying disease markers or studying disease progression is generally recognized in the art as useful. This does not impute a specific, substantial and credible utility to the instant claims, however. The instant claims recite only analysis of gene expression data as it relates to "biological characteristics." The claims are not

limited to analysis of "massive amounts" of data, nor to genes and/or characteristics known to be correlated to disease, nor comparison of genes from different tissues (e.g. normal vs. abnormal or tissue from different disease stages), such that diseases may be studied. In fact, neither the genes nor the biological characteristics recited in the claims are limited to be from any particular organism, tissue, developmental stage, or disease state such that one skilled in the art would know whether any disease is, in fact, to be analyzed.

In response to the argument that the prior art of ZHENG US 6,263,287) does not recite a correlation step, it is noted that the claims of ZHENG recite steps significantly different from those of the instant claims, including comparison to a common reference frame, and clustering. Further, applicant is reminded that each patent application is examined on its own merits; again, it is noted that the claims of ZHENG recite steps not found in the instant claims. In addition, while a reference is relied upon for the totality of its teachings, applicant is reminded that parts of the disclosure of ZHENG other than the claims are the teachings relied upon in the rejection set forth under 35 USC 102 and 103. None of this negates the rejection of the *instant* claims for lack of utility.

For all the reasons set forth above and set forth in the previous office action, the examiner maintains that the claims lack utility.

Claims 1-7, 13-22, 28-37 and 43-45 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either an asserted utility or a well established utility for the reasons set forth above, one skilled in

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the art clearly would not know how to use the claimed invention. Specifically, one skilled in the art would not know what to "do" with the results of the analysis. As the utility rejection is maintained, above, so is the lack of enablement rejection.

Claim Rejections - 35 USC § 102

The rejections under 35 USC 102 are hereby withdrawn in view of the claim amendments filed 5/17/05.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Applicant's arguments with respect to claims 1-7, 13-22, 28-37, and 43-45 have been considered but are moot in view of the new ground(s) of rejection set forth below. The new rejections are necessitated by amendment.

Claims 1-4, 6, 13-19, 21, 28-34, 36, and 43-45 are rejected under 35 103(a) as being unpatentable over ZHENG et al. (US 6,263,287) in view of The Gene Ontology Consortium; hereinafter GOC (Nature Genetics (May, 2000) Volume 25, pages 25-29).

ZHENG teaches a method, system, and program for manipulation and analysis of gene expression data wherein gene expression data is received/provided, and the

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data is clustered with regard to at least one biological characteristic, which may include tissue origin or genomic information about the gene (abstract and col. 2, lines 18-52), as in claims 1-2, 4, 6, 16-17, 19, 21, 31-32, 34 and 36. ZHENG teaches use of SQL (col. 1, lines 61-63), as in claims 15, 30 and 45. ZHENG teaches use of data from Genbank and other databases (col. 10), and teaches further analysis of the clustered data (col. 12, lines 40-45 and col. 15, lines 15-67), as in claims 3, 13-14, 18, 28-29, 33, and 43-44. ZHENG does not teach biological characteristics described using a gene ontology system.

GOC teaches a gene ontology system for describing biological characteristics for a variety of organisms (p. 25) and teaches that this ontology system may be used in analysis and annotation of gene expression data (p. 28). GOC also teaches that ontology is a vital tool enabling researchers to turn data into knowledge (p. 27).

It would have been obvious to one of ordinary skill in the art at the time of invention to have described the biological characteristics in the method of ZHENG using the ontology system of the GOC where the motivation would have been to improve the method using a tool which allows a flexible and dynamic way of comparing homologous gene sequences using a common vocabulary, as taught by GOC (p. 28).

Claims 5, 20, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over ZHENG et al. (US 6,263,287) and The Gene Ontology Consortium; hereinafter GOC (Nature Genetics (May, 2000) Volume 25, pages 25-29) as applied to claims 1-4,

6, 13-19, 21, 28-34, 36, and 43-45 above, in view of ROCKE et al. (US 2002/0111742).

ZHENG and the GOC make obvious a method, program and computer system for analyzing gene expression data, as set forth above. GOC further teaches hierarchical clustering (Fig. 2), but ZHENG and the GOC do not specifically teach multiple dimension clustering.

ROCKE teaches classifying high dimensional data in methods of gene expression analysis (abstract and paragraph 85).

It would have been obvious to one of skill in the art at the time of invention to have performed the dimension reduction of ROCKE on large gene expression databases before clustering in the method of ZHENG and GOC where the motivation would have been to facilitate clustering and permit accurate "classification" of the data, as taught by ROCKE (paragraphs 7 and 17). One skilled in the art would reasonably have expected success in combining ROCKE's dimension reduction with ZHENG and GOC's clustering because all teach analyzing large amounts of gene expression data in order to correlate differential gene expression with tissue or functional specificity (see ZHENG, col. 15, GOC, Fig. 2, and ROCKE, paragraphs 85-86).

Claims 1-4, 6-7, 13-19, 21-22, 28-34, 36-37 and 43-45 are rejected under 35 U.S.C. 103(a) as obvious over GARNER et al. (US 2003/0033290) and OGATA et al. (Nucleic acids Res. (1999) vol. 27, no. 1, pp. 29-34) in view of The Gene Ontology Consortium; hereinafter GOC (Nature Genetics (May, 2000) Volume 25, pages 25-29).

GARNER teaches a method, program and system for analysis of genetic databases (abstract) wherein gene expression data is obtained and clustered according to selected biological characteristics, including genomic information and biological function (paragraphs 8, 82 and 151-152), as in claims 1-2, 4, 6, 16-17, 19, 21, 31-32, 34, and 36. GARNER teaches that the information derived from the clustering analysis may be used to select or recommend genes for further analysis (paragraph 257), as in claims 3, 18, and 33. GARNER teaches a variety of databases (paragraph 158), including KEGG, and use of SQL software (paragraph 150), as in claims 13-15, 28-30, and 43-45).

OGATA provides support that KEGG comprises information with regard to orthologous genes (p. 33, left column), therefore GARNER's teaching of KEGG is inherently a teaching for biological information comprising orthologous genes, as in claims 7, 22, and 37.

Neither GARNER nor OGATA teach biological characteristics described using a gene ontology system.

GOC teaches a gene ontology system for describing biological characteristics for a variety of organisms (p. 25) and teaches that this ontology system may be used in analysis and annotation of gene expression data (p. 28). GOC also teaches that ontology is a vital tool enabling researchers to turn data into knowledge (p. 27).

It would have been obvious to one of ordinary skill in the art at the time of invention to have described the biological characteristics in the method of GARNER and OGATA using the ontology system of the GOC where the motivation would have been

to improve the method using a tool which allows a flexible and dynamic way of comparing homologous gene sequences using a common vocabulary, as taught by GOC (p. 28).

Conclusion

Claims 1-7, 13-22, 28-37, and 43-45 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
8/4/05